

**REMARKS**

With entry of this amendment, claims 33 and 68-106 are pending in this application. Of these, claims 33 and 68-100 stand rejected, and claims 101-106 have been newly added. As an initial matter, claims 93-100 have been amended simply to correct their dependencies from independent claim 80 to independent claim 92. No amendments have been made for the purpose of overcoming any current or anticipated subsequent rejection. Based on the foregoing amendments and following remarks, reconsideration and allowance of this application is respectfully requested.

**Claim Rejections-35 U.S.C. §102**

**Ryan**

Claims 33 and 68-100 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,830,217 (“Ryan”). Without acquiescence that Ryan is, indeed, §102(e) prior art, and without prejudice to antedate the filing date of Ryan should it become necessary, Applicant respectfully traverses this rejection, since Ryan does not disclose each and every element required by these claims, as amended.

In particular, independent claim 33 requires the distal tip member to distally extend beyond the distal extremity of the tubular body. Contrary to the Examiner’s position, the fairing of the Ryan device, which the Examiner characterizes as the distal tip member, does not extend beyond the distal extremity of the tubular body 3. Although the Examiner characterizes the distal end 5 of the balloon 2 as being the distal extremity of the tubular body 3, this characterization is contrary to the plain meaning of the term “distal extremity.” According to The American Heritage College Dictionary, Third Edition, the term “extremity” means “the outermost or farthest point or portion,” which when qualified by the term distal, means the distal most point or portion. With respect to the Ryan device,

the distal most point or portion of the catheter tube 3 is clearly distal to the fairing 15 (as the distal tip member), as illustrated in the attached redlined drawing. Thus, it follows that the fairing 15 does not extend beyond the distal extremity of the catheter tube 3. Applicant realizes that Ryan characterizes the distal end 5 of the balloon 2 as being the distal tip of the catheter (see col. 3, line 44), but this does not make it the distal extremity of the catheter tube 3.

Independent claim 80 precludes the distal member from hindering the deployment of the occlusion device prior to undergoing bioabsorption or dissolution. Prior to bioabsorption or dissolution, the fairing 15 of Ryan (as the distal tip member) clearly hinders the deployment of the occlusion device 1. In referring to the fairing 15, Ryan specifically states that the “material serves to secure the stent to the balloon, and this helps prevent any unintentional slippage or early release of the stent.” (see col. 5, lines 6-8). Ryan continues, stating that “the material is used solely to secure the stent to the balloon.” (see col. 5, lines 18-19). Thus, by design, the fairing 15 hinders deployment of the occlusion device. The Examiner refers to col. 8, lines 20-27 for the proposition that the occlusion device may be deployed even before the tip dissolves. However, this excerpt indicates that the stent can be expanded while the fairing 15 is partially intact—not that the stent can be expanded prior to the fairing 15 undergoing bioabsorption or dissolution. Clearly, if the fairing 15 is partially intact, it is already undergoing bioabsorption or dissolution, and thus, it cannot be said that the occlusion device may be deployed prior to the time that the fairing 15 undergoes bioabsorption or dissolution.

Even if the stent of the Ryan device is capable of deploying prior to the fairing 15 undergoing bioabsorption or dissolution, such deployment would still be hindered by the fairing 15. The Examiner appears to be under the impression that being capable of performing an action precludes a finding that such action is hindered. However, this logic contradicts the plain meaning

of the term “hinder,” which means “1. to be or get in the way of” or “2. to obstruct or delay the progress of.” (See The American Heritage College Dictionary, Third Edition). The fact that stent is at least partially encased within the fairing 15 will obviously get in the way, obstruct, or delay its deployment prior to the fairing 15 undergoing bioabsorption or dissolution—especially since the fairing 15 is designed to prevent premature deployment of the stent as discussed above.

Independent claim 92 requires the distal tip member to be configured to remain fixedly secured to the distal portion of the tubular body during the entire bioabsorption or dissolution process. Nowhere in Ryan is it disclosed that the fairing 15 is configured to remain fixedly secured to the tubular body 3 during the entire bioabsorption or dissolution process. Citing col. 6, lines 19-23, and col. 8, lines 18-27, the Examiner states that the fairing 15 “may completely, partly, or not at all dissolve, therefore, some of the tip will remain on the tubular body at all times.” However, these excerpts merely state that the stent can be deployed before the tip member is entirely dissolved. Ryan does not disclose that that fairing 15 is configured to be secured to the tubular body during the entire bioabsorption or dissolution process. Indeed, the hollow and delicate nature of the fairing 15 would most likely cause it to fall off of the tubular body sometime during the bioabsorption or dissolution process. Significantly, the claim language requires the distal tip member to remain on the tubular body during the entire bioabsorption or dissolution process—not merely sometime during the process, as the fairing 15 of the Ryan device might do.

Thus, Applicant submits that independent claims 33, 80, and 92, as well as the claims depending therefrom (claims 68-79, 81-91, and 93-100), are not anticipated by Ryan, and as such, respectfully requests withdrawal of the §102 rejection of these claims based on this reference.

Roberts

Claims 33 and 68-100 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,603,698 (“Roberts”). Applicant respectfully traverses this rejection, since Roberts does not disclose each and every element required by these claims, as amended.

In particular, independent claim 33 requires that the distal tip member be fixedly secured to the distal portion of the tubular body. Independent claims 80 and 92 require that the distal tip member be configured to remain fixedly secured to the distal portion of the tubular body during the entire bioabsorption or dissolution process. The Examiner has concluded that the distal tip 26 of the Roberts device is configured to be fixedly secured to the catheter body 4 even though it is designed to slide off of the catheter body 4 during the bioabsorption or dissolution process. However, this interpretation is completely contrary to the plain language of the term “fixedly secured.” The term “fixed” means “1. Firmly in position; stationary,” “2. determined; established; set,” or “3. Not subject to change or variation; constant.” (See The American Heritage College Dictionary, Third Edition) Thus, the claim language “fixedly secured to the distal portion of the tubular body” means that the distal tip 26 of the Roberts device be secured to the catheter body 4 firmly in position, or secured to the catheter body 4 in a stationary, determined, established, or set manner, or secured to the catheter body 4 such that it is not subject to change or variation or is constant. However, the only time that the distal tip 26 meets this criteria is prior to the bioabsorption or dissolution process. The fact that the distal tip is “selectively dislodgeable, and can, or may be removed, or is removable” does not change this fact. At the time that the distal tip is being bioabsorbed or dissolved, it is capable of sliding relative to the catheter body 4, and is thus not fixedly secured to the catheter body 4.

4. Applicant agrees with the Examiner that method steps are irrelevant in a product claim, but the

term “fixedly secured” is functional language that is relevant to the claims and must be given patentable weight.

Although claim 33 does not require the distal tip member to be fixedly secured to the tubular body during the bioabsorption or dissolution process, it does require the distal tip member to distally extend beyond the distal extremity of the tubular body. Thus, even though the Examiner states that the distal tip 26 may distally extend beyond the distal extremity of the catheter body 4 during the bioabsorption or dissolution process, at this point, the distal tip 26 slides relative to the tubular body and therefore is not configured to be fixedly secured to it. With regard to claims 80 and 92, the distal tip 26 simply is not configured to be fixedly secured to the catheter body 4 during the bioabsorption or dissolution process.

Thus, Applicant submits that independent claims 33, 80, and 92, as well as the claims depending therefrom (claims 68-79, 81-91, and 93-100), are not anticipated by Roberts, and as such, respectfully requests withdrawal of the §102 rejection of these claims based on this reference.

#### Claim Rejections-35 U.S.C. §103

Claims 33, 68-69 and 72-79 stand rejected under 35 U.S.C. §103 as being obvious over Roberts. Applicant traverses this rejection, since Roberts does not disclose, teach, or suggest the combination of elements required by these claims.

The Examiner states that even though Roberts does not disclose the tip 26 as being distal to the distal extremity 8 of the tubular body 4, it would have been obvious do to so, “since it has been held that a mere relocation of parts of an invention involves only routine skill in the art.” However, the fact that a prior art device can be merely modified using only routine skill in the art, does not render a claimed invention obvious in view of the modified prior art device. There must be more in

the form of a suggestion or motivation to modify the prior art device. (M.P.E.P. §2143). In this case, there is no suggestion to place the tip 26 so that it is distal to the distal extremity of the tubular body. In fact, such a modification would completely eviscerate the disclosed function of the flexible distal end 8, which is to provide flexibility to the distal end of the device to prevent tissue trauma. (see col. 4, lines 13-19).

Thus, Applicant submits that independent 33, 68-69 and 72-79 are not obvious in view of Roberts, and as such, respectfully requests withdrawal of the §103 rejections of these claims.

#### New Claims

Newly added claims 101-106, which find support in the originally filed application, are believed to be patentable over the prior art. In particular, claims 101-106 depend from respective independent claims 33, 80, and 92, which are believed to be patentable as discussed above. Furthermore, claims 101-103 additionally require that the distal tip member be configured for not sliding off of the tubular body during the bioabsorption or dissolution process. In contrast, the distal tip 26 of the Roberts device is configured for sliding off of the catheter body 4 during the bioabsorption or dissolution process. Claims 104-106 additionally require the distal tip member be configured for remaining intact during the bioabsorption or dissolution process. In contrast, the fairing 15 of the Ryan device is not so configured.

#### Conclusion

Based on the foregoing, it is believed that all claims are now allowable and a Notice of Allowance is respectfully requested. If the Examiner has any questions or comments regarding this

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2024730-7012833001  
(PC10247C)

amendment, the Examiner is respectfully requested to contact the undersigned at (714) 830-0600.

Respectfully submitted,

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Dated: December 14, 2004

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